

DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF EMERGENCY AND SECOND PROPOSED RULEMAKING

The Director of the Department of Health Care Finance (DHCF), pursuant to the authority set forth in an Act to enable the District of Columbia to receive federal financial assistance under Title XIX of the Social Security Act for a medical assistance program, and for other purposes, approved December 27, 1967 (81 Stat. 744; D.C. Official Code § 1-307.02 (2016 Repl. & 2019 Supp.)), and the Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109; D.C. Official Code § 7-771.05(6) (2018 Repl.)), hereby gives notice of the adoption, on an emergency basis, of an amendment to Chapter 9 (Medicaid Program) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR).

On May 5, 2017, DHCF published an initial Notice of Proposed Rulemaking to amend Section 997 (Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)) of Chapter 9 of Title 29 of the DCMR in the *D.C. Register* at 64 DCR 004235 (May 5, 2017). DHCF received comments on those proposed rules (see below), and after review of those comments and in consideration of other changes that are needed for federal compliance purposes, DHCF is issuing this emergency and second proposed rulemaking to further amend Section 997 and create a new Section 998 (Medical Alert Devices and Services) to Chapter 9 of Title 29 DCMR.

These emergency and second proposed rules update reimbursement standards for DMEPOS provided under the District of Columbia Medicaid Program State Plan's Home Health benefit, to comply with federal requirements codified at 42 CFR § 440.70. The new Section 998 establishes District Medicaid coverage of a medical alert devices and services benefit. Section 998 describes the scope of items and services covered under the medical alert devices and services benefit, sets forth the eligibility criteria for coverage, and specifies the requirements for providers of this benefit.

In alignment with federal requirements, these emergency and proposed rules clarify that covered DMEPOS may be provided in any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/IID, or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Consistent with federal guidance, this emergency and proposed rulemaking removes the current restriction limiting Medicaid DMEPOS coverage to DMEPOS items suitable for use in the home and replaces it with new language that provides that DMEPOS is suitable for use in any non-institutional setting in which normal life activities take place, and clarifies that requests for DMEPOS items may not be denied on the grounds that they are for use outside of the home.

Also in alignment with the federal requirements, these emergency and proposed rules add a face-to-face encounter requirement for Medicaid coverage of DMEPOS, mandating that the face-to-face encounter must be related to the primary reason the beneficiary requires DMEPOS, must occur no more than six (6) months prior to the start of services, and must be documented by the ordering health practitioner.

Of note for providers and beneficiaries, DHCF is proposing changes to administration of the Medicaid program to ensure the accessibility of services to Medicaid beneficiaries if the risk of coronavirus disease (COVID-19) or any other public health emergency in the District requires quarantine of beneficiaries or impedes access to DMEPOS services. In accordance with recent emergency legislation and Mayor's Order 2020-052, DHCF has made changes to DMEPOS service requirements via guidance published in the *D.C. Register* and the DHCF website during the public health emergency prompted by COVID-19, as declared by the Mayor. Pursuant to the Mayor's Order 2020-052, DHCF will implement a number of service delivery, prior authorization, and service eligibility changes for DMEPOS services during the public health emergency.

These rules are also updated to establish Medicaid coverage and reimbursement requirements for providers of medical alert devices and services under the State Plan. Medical alert devices and services are included under the District of Columbia Medicaid Home Health services benefit, to be effective October 1, 2020. Under the new proposed State Plan benefit, medical alert devices and services will include coverage of Personal Emergency Response System (PERS) devices and services, as well as medication management devices and services. DHCF's proposed State Plan coverage of Medical alert devices and services aligns with changes DHCF is proposing to the District's 1915(c) Home and Community Based-Services Waiver for the Elderly and Persons with Physical Disabilities (EPD Waiver), which will also be effective October 1, 2020.

After the initial DMEPOS Notice of Proposed Rulemaking was published in the *D.C. Register*, DHCF received comments on the proposed rulemaking from Disability Rights DC at University Legal Services (DRDC). DHCF carefully considered the comments received, and for the reasons detailed below, concluded that no substantive changes were necessary in response to DRDC's comments. The summary below describes DHCF's response to DRDC's comments and also changes DHCF is making pursuant to federal requirements.

Applicability of Federal Requirements at 42 CFR § 440.70

DRDC asserted that the federal requirements at 42 CFR § 440.70 applied only to services offered under Medicare and therefore did not affect the District's Medicaid program.

DHCF Response: Because 42 CFR § 440.70, which defines the amount, duration and scope of home health services that may be offered under the Medicaid program, is contained within the federal regulations governing Medicaid, these federal requirements apply and must be complied with by State Medicaid agencies. For this reason, DHCF declines to make any changes in response to DRDC's comments.

Coverage of DMEPOS for Residents of Nursing Facilities or ICF/IIDs

DRDC expressed concern that the proposed rules would abolish Medicaid reimbursement of DMEPOS for beneficiaries residing in a nursing facility or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), in conflict with federal requirements and other DHCF regulations. DRDC asserted that DHCF should delete § 997.17(a) in the proposed rule, which excludes coverage of DMEPOS provided under the home health services benefit for beneficiaries residing in a hospital, nursing facility, or ICF/IID.

DHCF Response: DHCF would like to emphasize that DMEPOS for District Medicaid beneficiaries residing in a nursing facility or ICF/IID will continue to be covered. The federal regulation at 42 CFR § 440.70 governs DMEPOS provided under the State Plan Home Health services benefit and the referenced language included in this rulemaking comes directly from the federal regulation. With the exception of those home health services that are not covered by an ICF/IID, as set forth in 42 CFR § 483.460, this federal rule does not affect reimbursement for DMEPOS for beneficiaries residing in a facility-based setting. DHCF is reformatting this rulemaking to simplify its structure. Requirements originally proposed in § 997.17(a) remain but are incorporated into § 997.3.

Applicability of Federal Requirements at 42 CFR § 483.460

DRDC asserted that 42 CFR § 483.460 governs conditions of participation in Medicare and is not relevant to these rules.

DHCF Response: DHCF respectfully disagrees with DRDC's interpretation, as 42 CFR § 483.460 sets forth the healthcare services that an ICF/IID provider must furnish in order to participate in the Medicaid program. Specifically, this set of requirements are part of Subpart I (Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities) or Part 483 (Requirements for States and Long Term Care Facilities). Under this Subpart, the Secretary is interpreting the definition of nursing facilities and ICF/IIDs under Title XIV of the Social Security Act, which governs Medicaid.

As DRDC noted in its comments, reimbursement for DMEPOS provided to beneficiaries residing in a nursing facility or ICF/IID is addressed in separate regulations contained in Chapters 65 and 41 of Title 29 of the DCMR, respectively. These regulations governing reimbursement for DMEPOS provided in a facility-based setting are not affected by the federal requirements at 42 CFR § 440.70 for DMEPOS offered under the State Plan Home Health services benefit. DMEPOS for District Medicaid beneficiaries residing in a nursing facility or ICF/IID will continue to be covered. Supplies and equipment for general use in a facility are not the subject of this rulemaking and are not subject to the requirements set forth in this Chapter.

CMS Guidance Regarding Reimbursement of DMEPOS for Residents of Nursing Facilities or ICF/IIDs

DRDC cited a January 2017 bulletin issued by the Centers for Medicare and Medicaid Services (CMS) on improving access to DMEPOS for individuals dually eligible for Medicare and Medicaid in support of the idea that Medicaid coverage of DMEPOS is broader than Medicare coverage, and that states cannot use the Medicare DMEPOS coverage requirements as a complete proxy for their state Medicaid programs.

DRDC also asserted that that CMS revisions to 42 CFR § 440.70 were issued in part to ensure that DMEPOS provided under the Home Health services benefit could be provided to Medicaid beneficiaries who were not homebound (which is a Medicare requirement for home health services), and could be provided in "any setting in which normal life activities take place" other

than a hospital, nursing facility, ICF/IID or other setting in which Medicaid reimbursement could be made for inpatient services, including room and board. These settings criteria are much broader than under Medicare, which restricts DMEPOS to use in the beneficiary's home. CMS wanted to ensure that state Medicaid programs were furnishing DMEPOS and other Home Health benefits in a wider range of settings than those allowable under Medicare and not simply relying on the Medicare criteria when authorizing these services.

DHCF Response: DHCF agrees with DRDC restatement of CMS purpose in issuing the updating guidance. DHCF is implementing its program in accordance with these updated requirements and not proposing further or more restrictive changes.

Beneficiary Access to Medically Necessary DMEPOS During a Nursing Facility or ICF/IID Stay

DRDC expressed concern that the proposed rules restrict beneficiaries' access to medically necessary DMEPOS during stays in a nursing facility or ICF/IID, severely undermining their rehabilitation and resulting in serious health risks, in conflict with the mandates of the Nursing Home Reform Act at 42 USC 1396r and the District's obligations under *Olmstead v. L.C.*, 527 U.S. 581 (1999), and Title II of the Americans with Disabilities Act (42 U.S.C. §§ 12131 – 12165).

DHCF Response: As noted above, DMEPOS for District Medicaid beneficiaries residing in a nursing facility or ICF/IID will continue to be covered. Supplies and equipment for general use in a facility are not the subject of this rulemaking and are not subject to the requirements set forth in this Chapter. Beneficiaries residing in nursing facilities and ICF/IIDs receive comprehensive services that are provided and reimbursed in accordance with separate Chapters under Title 29 DCMR. DHCF is not proposing further changes at this time.

Availability of DMEPOS Providers

DRDC expressed concern that, as proposed, §§ 997.1 and 997.2 of the proposed rule did not adequately ensure the availability of DMEPOS providers and timely access to DMEPOS for beneficiaries whose providers go out of business. To address this issue, DRDC advocated for the addition of a requirement that a DMEPOS provider must give notice prior to the closure of its business.

DHCF Response: DHCF is committed to maintaining a robust network of providers for services delivered under the State Plan. DHCF regularly reviews provider screening and enrollment requirements to ensure requirements are balanced toward the goal of increasing access. DHCF will continue to monitor the experience of beneficiaries receiving DMEPOS but declines to make additional changes at this time.

Face to Face Requirement

DHCF is also making changes in response to federal requirements. As a result of the expansion of the settings in which Medicaid home health services, including DMEPOS, may be provided, the revisions to 42 CFR § 440.70 also required that health care providers ordering DMEPOS conduct a face-to-face encounter with the beneficiary to ensure that DMEPOS are appropriately

ordered and utilized, like other home health services. To comply with these revisions to the federal regulations governing Medicaid home health services, including DMEPOS, DHCF is incorporating the home health services face-to-face encounter requirement and setting criteria into these DMEPOS rules in §§ 997.3 and 997.4.

Emergency action is necessary for the immediate preservation of the health, safety, and welfare of District Medicaid beneficiaries eligible for and in need of covered DMEPOS, including medical alert devices and services. These rules are being enacted on an emergency basis to ensure that beneficiaries continue to have access to those items and services most appropriate to their individual care needs, health, and safety.

These emergency and second proposed rules correspond to a related State Plan Amendment (SPA), which requires approval by the Centers for Medicare and Medicaid Services (CMS). Accordingly, Section 998 of this rulemaking shall become effective on October 1, 2020, or on an alternative effective date established by CMS in its approval of the corresponding SPA, whichever is later.

These emergency rules were adopted on October 14, 2020, and shall remain in effect for not longer than one hundred and twenty (120) days from the adoption date or until February 11, 2021, unless superseded by publication of a Notice of Final Rulemaking in the *D.C. Register*.

The Director also gives notice of the intent to take final rulemaking action to adopt these rules not less than thirty (30) days after the date of publication of this notice in the *D.C. Register*.

Chapter 9, MEDICAID PROGRAM, of Title 29 DCMR, PUBLIC WELFARE, is amended as follows:

Section 997, DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES, is amended to read as follows:

- 997.1 The Department of Health Care Finance (DHCF), the single state agency for the administration of medical assistance programs authorized under Titles XIX and XXI of the Social Security Act, shall ensure the provision of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to qualified Medicaid beneficiaries in accordance with the requirements of this section and the D.C. Medicaid DMEPOS Provider Billing Manual. All providers of DMEPOS shall be enrolled as such by DHCF in accordance with Provider Screening and Enrollment regulations and policies and § 996 of Title 29 District of Columbia Municipal Regulations (DCMR).
- 997.2 DHCF shall ensure that each Medicaid beneficiary retains his/her freedom of choice of DMEPOS providers, in accordance with 42 CFR § 431.51.
- 997.3 To be eligible for Medicaid reimbursement of DMEPOS provided to a beneficiary under these rules, the following requirements shall be met:
- (a) The cost of the item shall be reasonable;

- (b) The item shall be ordered by a physician or other licensed practitioner of the healing arts operating within the scope of practice allowed under the District of Columbia Health Occupations Revision Act of 1985, as amended, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1201.01 *et seq.*) and implementing rules, as well as all other applicable federal and District laws;
- (c) The ordering practitioner shall be enrolled as a provider in the District Medicaid Program;
- (d) The ordering practitioner and DMEPOS provider shall provide their National Provider Identification (NPI) numbers on the prescription, DMEPOS Request and Prior Authorization Form (Form 719(A)), and claim;
- (e) In accordance with 42 CFR § 440.70, DMEPOS under the home health services benefit shall be provided to a beneficiary at his/her place of residence, or in any setting in which normal life activities take place.
- (f) DMEPOS shall not be provided to a beneficiary in the following settings:
 - (1) A hospital, nursing facility, or ICF/IID (except for DMEPOS in an ICF/IID that is not required to be provided by the facility under 42 CFR Part 483, Subpart I); or
 - (2) Any setting in which payment is or could be made under Medicaid for inpatient services that include room and board; and
- (g) The beneficiary's need for the DMEPOS shall be reviewed annually by a the ordering practitioner operating within the scope of practice as set forth under District law.

997.4

Prior to DHCF making any payment for DMEPOS, the following requirements must be met:

- (a) The ordering practitioner shall ensure that DHCF Form 719(A) Prior Authorization Request and any supporting documentation include, at minimum, descriptions of the following:
 - (1) The beneficiary's condition;
 - (2) The diagnosis related to the need for the DMEPOS item;
 - (3) Any complicating medical conditions;

- (4) The functional abilities and limitations of the beneficiary, using assessments based on the standards described in § 997.8;
 - (5) The anticipated duration of the condition;
 - (6) The physical examination findings; and
 - (7) The potential for rehabilitation, if applicable.
- (b) No more than six (6) months prior to the start of services, a face-to-face encounter with the beneficiary shall be conducted by one of the following practitioners:
- (1) The beneficiary's physician;
 - (2) A nurse practitioner working in collaboration with the beneficiary's physician;
 - (3) A physician assistant acting under the supervision of the beneficiary's physician; or
 - (4) For beneficiaries admitted to home health immediately after an acute or post-acute stay, the attending acute or post-acute physician.
- (c) The ordering physician or allowed non-physician practitioner shall document that there was a face-to-face encounter with the beneficiary in accordance with the following requirements:
- (1) The face-to-face encounter must be related to the primary reason the beneficiary requires DMEPOS and must occur no more than six (6) months prior to the start of services; and
 - (2) The order must indicate the name of the practitioner who conducted the face-to-face encounter and the date of the encounter.

997.5 For a beneficiary up to twenty-one (21) years of age, who is entitled to the early and periodic screening, diagnosis, and treatment (EPSDT) benefit, covered items shall be limited to DMEPOS that are included within the scope of the definition set forth in Section 1905(r) of the Social Security Act (42 USC § 1396d(r)).

997.6 Medicaid reimbursement of DMEPOS shall require prior authorization by DHCF or its designee for the following:

- (a) DMEPOS items that exceed specific criteria and/or require prior authorization, as set forth in the D.C. Medicaid Provider Billing Manual and D.C. Medicaid Fee Schedule, available online at www.dc-medicaid.com;

- (b) DMEPOS items that are billed using miscellaneous codes or that require manual pricing;
- (c) Items of durable medical equipment (DME) that exceed five-hundred dollars (\$500) in purchase price, unless exempted from the requirement as indicated on the fee schedule;
- (d) Customized equipment; and
- (e) DME, prosthetics, and orthotics, outside of the warranty period, that require repair or replacement.

997.7 For items that require prior authorization in order to be reimbursed by Medicaid, as set forth in § 997.6, the following tasks shall be completed:

- (a) The prescribing clinician, as identified on the prescription provided in accordance with § 997.3(b), shall complete the clinical portion of DHCF Form 719(A) and provide the form to the DMEPOS provider for completion;
- (b) The DMEPOS provider shall present the completed Form 719(A), including the corresponding prescription, to DHCF or its designee for approval; and
- (c) The DMEPOS provider shall collect and submit supporting documentation and invoices to DHCF or its designee for review and approval.

997.8 DHCF or its designee shall use national standards, such as InterQual or other nationally recognized assessment tools, to assess the reasonableness and necessity of all DMEPOS items that require prior authorization.

997.9 A provider shall not receive Medicaid reimbursement for a DMEPOS item requiring prior authorization under § 997.6, if the item is delivered before DHCF or its designee has issued a prior authorization.

997.10 To receive Medicaid reimbursement for DMEPOS, a qualified physician or other practitioner of the healing arts, operating within the scope of practice outlined in the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986, as amended (D.C. Law 6-99; D.C. Official Code §§ 3-1201.01 *et seq.*) and implementing rules, shall review a beneficiary's continued need for any DMEPOS item as appropriate based on the beneficiary's condition, but on at least an annual basis, subject to the following exception:

- (a) DHCF shall not require a review of a beneficiary's continued need for DMEPOS in the case of a child with respect to either prescribed oxygen or oxygen equipment or both.

- 997.11 Information set forth in the D.C. Medicaid DMEPOS Provider Billing Manual shall govern specific criteria regarding Medicaid reimbursement for the following categories of DMEPOS:
- (a) Mobility assistive equipment; and
 - (b) Oxygen and oxygen equipment.
- 997.12 Where a previously approved prior authorization period has expired, a DMEPOS provider shall not provide to a beneficiary any new item for which prior authorization is required, as set forth in § 997.6, until DHCF or its designee has issued a new prior authorization number for the new period. If a prior authorization has previously been issued for an item to a different DMEPOS provider, the current DMEPOS provider shall include a reference to the original prior authorization number on the Form 719(A) submitted to DHCF or its designee for approval.
- 997.13 Medicaid reimbursement of DMEPOS shall be subject to the following standards:
- (a) DHCF shall establish maximum reimbursement rates for items included under the DMEPOS benefit and shall set forth these rates in the D.C. Medicaid Fee Schedule, available online at www.dc-medicaid.com;
 - (b) All rates for DMEPOS shall be subject to a pricing analysis by DHCF or its designee. The pricing analysis may consider the following:
 - (1) Beneficiary's condition;
 - (2) Brand comparison;
 - (3) Anticipated duration of beneficiary's need for the item;
 - (4) Warranty coverage and conditions;
 - (5) Medicare local coverage and pricing determinations;
 - (6) Pricing under other jurisdictions' Medicaid programs;
 - (7) Usual and customary pricing; or
 - (8) Discounts;
 - (c) For any DMEPOS item that is determined to be covered under the District Medicaid program, but is not included on the D.C. Medicaid Fee Schedule, DHCF shall price the item using the process described in § 997.13(b);

- (d) For a beneficiary enrolled in both Medicare and Medicaid, a DMEPOS provider shall first bill the Medicare program when providing any item to the beneficiary. If Medicare denies the claim, the provider may then submit the remittance advice along with the claim to DHCF or its designee. A DMEPOS provider shall not bill a dual eligible beneficiary for any amount not paid by Medicare. Failure to adhere to these requirements may subject the DMEPOS provider to termination of its Medicaid Provider Agreement;
- (e) If a prescribing clinician or DMEPOS provider receives a discount for an item ordered for use by a Medicaid beneficiary, the prescribing clinician and/or DMEPOS provider shall subtract the amount of the discount from the amount for which reimbursement is sought prior to submitting the claim to DHCF. Failure to comply with the requirements of this paragraph may result in denied claims, temporary suspension of payments, or termination of the Medicaid Provider Agreement;
- (f) A DMEPOS provider shall provide original documentation reflecting all discounts that apply to the cost of any item provided to a Medicaid beneficiary;
- (g) A DMEPOS provider shall produce proof of delivery for all items that are provided to a Medicaid beneficiary, which may include:
 - (1) Receipts that are signed by the beneficiary who requires DMEPOS, or his or her legal representative; or
 - (2) Delivery confirmation; and
- (h) Except for items deemed necessary under the EPSDT benefit, the following shall not be covered under the DMEPOS benefit:
 - (1) Replacement of an item while it is still under warranty or before the item meets the associated life expectancy, unless prior authorization is obtained;
 - (2) Ventilators;
 - (3) Acquisition, maintenance, or repair of DME, prosthetic, and orthotic items that do not require prior authorization or are for general use in an institutional provider facility where a beneficiary resides;
 - (4) Consumable medical supplies for general or non-beneficiary specific use in an intermediate care facility for individuals with intellectual disabilities (ICF/IID);

- (5) Items solely for comfort and convenience of the beneficiary or his/her caregivers, such as air conditioners;
- (6) Home or vehicle modifications covered under waiver programs operating pursuant to Section 1915(c) of the Social Security Act;
- (7) Rehabilitative equipment, for beneficiaries age twenty-two (22) and older, if designed to bring a beneficiary into an upright position to stimulate vestibular function or balance; and
- (8) Supplies and other DME items used by personnel of a home health agency during the course of a home visit.

997.14

To be eligible for Medicaid reimbursement, the delivery of DME is subject to the following requirements:

- (a) DME consists of equipment that:
 - (1) Can withstand repeated use;
 - (2) Is primarily and customarily used to serve a medical purpose;
 - (3) Is generally not useful to a beneficiary in the absence of a disability, illness, or injury;
 - (4) Is appropriate for use in any setting in which normal life activities take place, as defined at 42 CFR § 440.70(c)(1); and
 - (5) Is expected to have a useful life of at least three (3) years;
- (b) For a beneficiary age zero (0) through twenty-one (21), DME shall also include equipment used in natural environments;
- (c) For purposes of this section, for a beneficiary age twenty-two (22) and older, the home shall also include an assisted living center, home for the aged, or other senior living facility;
- (d) DME shall be rented if the beneficiary's medical condition is anticipated to last six (6) months or less. Rental rates shall include costs of maintenance and servicing rented items. Except for fees associated with maintaining and servicing oxygen equipment, DHCF shall not reimburse for maintenance and servicing of a rented item. Any provider of rental DME seeking Medicaid reimbursement shall adhere to the following:
 - (1) Maintain and repair any DME item being rented to a Medicaid beneficiary;

- (2) Accept returns of substandard or unsuitable items; and
 - (3) Provide to the beneficiary a replacement item that meets the specifications of the originally prescribed item and in such a manner as to minimize the burden on the beneficiary;
- (e) The total reimbursement available for DME obtained through rental shall not exceed the purchase price of the item. At the time when rental payments equal the purchase price of the item, the item shall be considered purchased and shall become the property of the beneficiary;
- (f) DME shall be purchased only under the following circumstances:
- (1) If the beneficiary's medical condition is anticipated to last more than six (6) months and the equipment does not require frequent servicing or repair; or
 - (2) If the beneficiary's medical condition requires customized equipment;
- (g) DME that is purchased shall become the property of the beneficiary for whom it was prescribed;
- (h) In accordance with § 997.6(e), DHCF or its designee, shall prior authorize any repairs to purchased equipment. A DME provider shall be required to submit to DHCF or its designee a copy of the warranty for the item needing repair within thirty (30) days of the date of the request for repair;
- (i) When DME is purchased for use by a beneficiary, and is under warranty, the DME provider shall be required to pay reasonable charges for maintenance and servicing of the item;
- (j) A DME provider shall first seek to have a covered item maintained, serviced, or repaired by the manufacturer in accordance with the warranty;
- (k) DHCF shall reimburse a DME provider for charges related to parts and labor that are not otherwise covered under a manufacturer or supplier warranty;
- (l) When a beneficiary's DME item is undergoing repair, a DME provider may receive reimbursement for a substitute DME item if prior authorized by DHCF or its designee. Prior authorization of a substitute DME item is subject to the following conditions:
- (1) The substitute DME item must be reasonable and necessary;

- (2) The frequency of use, or the number of units requested, of the substitute DME item must be consistent with code definitions;
 - (3) The total cost to rent the substitute DME item must not exceed the purchase price; and
 - (4) The substitute DME item shall be prior authorized for a period not to exceed two (2) months, except that a substitute DME item provided during repair of customized equipment shall be prior authorized for a period not to exceed six (6) months;
- (m) A DME provider/supplier responsible for maintaining, servicing, or repairing a customized item that requires repair or replacement shall perform the following:
- (1) Obtain an estimated repair time from the manufacturer and provide the information to the Medicaid beneficiary and his/her caregivers; and
 - (2) Provide the beneficiary a substitute DME item with specifications that are as similar to the customized item as possible, if needed or requested, in accordance with prior authorization requirements;
- (n) A DME provider of a substitute DME item shall not continue to bill DHCF for the substitute DME item once the beneficiary receives the repaired or replacement DME item;
- (o) Prior to or at the time of delivery of DME, the DME provider shall perform an on-site evaluation of the beneficiary's home, if applicable, in order to verify that the beneficiary can adequately maneuver the item that is provided considering the physical layout, doorway widths and thresholds, and surfaces. There shall be a written report of this evaluation, and the provider shall make it available upon DHCF's request. Documentation required under this section shall also be subject to the record keeping requirements of 29 DCMR § 996.9;
- (p) A prescribing clinician shall describe the clinical appropriateness of oxygen therapy by completing CMS Form 484 and submitting to DHCF, or its designee, along with any other required documentation. A beneficiary shall be eligible for oxygen therapy, including portable oxygen therapy, if his or her condition is supported by documentation of diagnosis and laboratory results reflecting any of the following conditions:

- (1) Severe lung disease, including but not limited to chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, and widespread pulmonary neoplasm; or
 - (2) Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy, including but not limited to pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache;
- (q) Oxygen therapy shall be subject to the following:
- (1) An authorization for oxygen therapy shall be valid for twelve (12) months for adult beneficiaries age twenty-two (22) and older, and six (6) months for children age zero (0) through twenty-one (21); and
 - (2) A prescriber of oxygen therapy shall be required to see a beneficiary in-person within a thirty (30) day period prior to the start of therapy in order to certify the need for the items/services;
- (r) Oxygen therapy shall not be covered for the following conditions:
- (1) Angina pectoris in the absence of hypoxemia;
 - (2) Breathlessness without cor pulmonale or evidence of hypoxemia;
 - (3) Severe peripheral vascular disease resulting in clinically evident denaturation in one or more extremities;
 - (4) Terminal illnesses that do not affect the lungs;
 - (5) Treatment of headache, including migraine; and
 - (6) Treatment of other health care conditions in which oxygen therapy is determined to be experimental or investigational; and
- (s) Diabetic testing meters shall be limited to those preferred items authorized pursuant to the D.C. Medicaid Diabetic Supplies program.
- 997.15 The delivery of prosthetics and orthotics shall be subject to the following requirements:
- (a) Covered prosthetics and orthotics include the following:

- (1) Devices that can replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, as described in § 997.15(b);
 - (2) Breast prostheses, including the surgical brassiere;
 - (3) Leg, arm, back, and neck braces;
 - (4) Artificial legs, arms, including stump cover or harness, where necessary;
 - (5) One pair of conventional eyeglasses or contact lenses furnished subsequent to cataract surgery that included insertion of an intraocular lens;
 - (6) Artificial eyes; and
 - (7) Therapeutic shoes, diabetic shoe inserts, splints, and supports.
- (b) Coverage of prosthetic and orthotic devices includes replacements that are required based on a change in a beneficiary's physical condition or the consumable nature of the item (e.g., ostomy supplies).
- (c) Replacement of prosthetic and orthotic devices shall be covered only when prescribed by a clinician meeting the requirements of § 997.3(b).
- (d) Covered prosthetic and orthotic devices shall not include the following items:
- (1) Intraocular lenses;
 - (2) Supplies and equipment related to ostomy care that is furnished by home health agency personnel during the course of a home visit; and
 - (3) Dental prostheses.

997.16 The delivery of supplies shall be subject to the following requirements:

- (a) Covered supplies consist of health care related items that:
- (1) Are required to address a specific medical disability, illness, or injury, and;
 - (2) Are appropriate for use in any setting in which normal life activities take place, as defined at 42 CFR § 440.70(c)(1);

- (b) Supplies include, but are not limited to:
- (1) Lancets;
 - (2) Gloves;
 - (3) Bandages;
 - (4) Enteral products; and
 - (5) Incontinence supplies.

A new Section 998, MEDICAL ALERT DEVICES AND SERVICES, is added to Chapter 9, MEDICAID PROGRAM, of Title 29 DCMR, PUBLIC WELFARE, as follows:

Section 998 MEDICAL ALERT DEVICES AND SERVICES

- 998.1 Medical alert devices and services include equipment, systems, and services which enable an individual to secure help in the event of an emergency or are used to provide an individual with reminders of medication or treatment schedules.
- 998.2 Medical alert devices and services are subject to the relevant authorization, delivery, and service requirements for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) set forth in 29 DCMR § 997, except as otherwise set forth in this section.
- 998.3 Providers of medical alert devices and services shall be enrolled in the District Medicaid program in accordance with the Provider Screening and Enrollment requirements described at 29 DCMR § 9400, except that such providers shall not be required to furnish Medicare-covered items or submit evidence of enrollment in the Medicare program.
- 998.4 Providers of medical alert devices and services shall comply with the requirements for DMEPOS set forth at 29 DCMR § 996, subject to the following exceptions:
- (a) A provider of medical alert devices and services is not required to furnish Medicare-covered items; and
 - (b) A provider of medical alert devices and services is not required to submit any evidence of enrollment in the Medicare program.
- 998.5 Providers enrolling as medical alert devices and services providers shall be required to demonstrate capacity to provide PERS services in accordance with the requirements set forth in § 998.7 as a condition of Medicaid enrollment.

- 998.6 Medicaid coverage of medical alert devices and services include, but are not limited to, the following:
- (a) PERS; and
 - (b) Medication management devices.
- 998.7 PERS shall be provided in accordance with the following requirements:
- (a) PERS is an electronic system that summons assistance for a beneficiary from a friend, relative, or an emergency services provider (police, fire department, or ambulance) and shall be available twenty-four (24) hours a day, seven (7) days a week.
 - (b) Each PERS system shall be comprised of the following two (2) basic elements:
 - (1) Equipment accessed or used by the beneficiary, including but not limited to a portable help button, motion detector; and
 - (2) A response center or responder to monitor the notifications.
 - (c) The PERS service shall be comprised of two (2) processes:
 - (1) Installation of the service unit; and
 - (2) On-going monitoring of the system;
 - (d) The units of service shall be as follows:
 - (1) One (1) unit per year for installation and testing of the PERS system; and
 - (2) Twelve (12) units per year for monthly rental, maintenance, and service fee;
 - (e) Each PERS provider shall:
 - (1) Provide in-home installation of all equipment necessary to make the service fully operational (including batteries);
 - (2) Provide beneficiary and representative instruction on usage, maintenance, and emergency protocol of the PERS;
 - (3) Provide equipment maintenance (both in-home and response center);

- (4) Provide response center monitoring and support, staffed by trained attendants, twenty-four (24) hours per day, seven (7) days per week;
 - (5) Conduct equipment testing, monitoring, and maintenance (both in-home and response center equipment);
 - (6) Conduct monthly service checks;
 - (7) Provide documentation of all services provided, beneficiary contacts, equipment and system checks, and equipment servicing;
 - (8) Make available emergency equipment repairs to the beneficiary on a twenty-four (24) hours per day, seven (7) days per week basis;
 - (9) Ensure that the beneficiary has functioning equipment within twenty-four (24) hours of notification of malfunction of the equipment;
 - (10) Allow the beneficiary to designate responder(s) who will respond to emergency calls. Responders may be relatives, friends, neighbors, or medical personnel; and
 - (11) Provide DHCF and beneficiary's direct care providers with reports in accordance with the manner and schedule determined by DHCF; and
- (f) Each PERS provider shall ensure that contractors are properly supervised and that the service provided is consistent with the beneficiary's person-centered service plan and plan of care.
- 998.8 Medicaid coverage of PERS shall be limited to beneficiaries who meet at least one of the following criteria:
- (a) Live alone; or
 - (b) Are alone for significant parts of the day.
- 998.9 Medicaid coverage of PERS shall be available for beneficiaries who are able to understand and demonstrate proper use of the system, based on the information provided by the LTCSS assessment.
- 998.10 Medication management devices shall include locked medication storage dispensers and systems that meet the following criteria:

- (a) Can be programmed to automatically dispense medications at predetermined times;
- (b) Include a reminder system to notify beneficiary when medication is to be taken, via audible alarms, lights, text messages, or voice messages;
- (c) Consist of a system designed to store a beneficiary's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the beneficiary's prescribed medications, to notify the beneficiary when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the beneficiary on the beneficiary's command, and to record a history of the event for the health care professional;
- (d) Include a remote medication management system composed of one or more of the following: clinical and communications software, a medication delivery unit, and/or medication packaging; and
- (e) Provide equipment and supplies used in the administration or monitoring of medication prescribed or ordered for a beneficiary by a qualified District Medicaid provider.

998.11 Medicaid coverage for medication management devices shall be limited to beneficiaries who:

- (a) Have one or more prescriptions for medication to be taken on an ongoing basis;
- (b) Require assistance with the management or administration of their prescribed medication(s);
- (c) Have sufficient physical and cognitive ability to take the medications at the prescribed time once dispensed from the device; and
- (d) Are not receiving the necessary medication management assistance from a Personal Care Aide, Adult Day Health Program, informal caregiver, or other in-person service provider.

998.12 Effective October 1, 2020, medical alert devices and service providers shall be reimbursed in accordance with the District of Columbia Medicaid Fee Schedule available online at www.dc-medicaid.com.

998.13 All future updates to the reimbursement rates for medical alert devices and services shall comply with the public notice requirements set forth under § 988.4 of Chapter 9 of Title 29 of the District of Columbia Municipal Regulations and provide notice and an opportunity for meaningful comment.

Comments on these rules should be submitted in writing to Melisa Byrd, Senior Deputy Director/State Medicaid Director, Department of Health Care Finance, Government of the District of Columbia, 441 4th Street NW, Suite 900, Washington, DC 20001, via telephone at (202) 442-8742, or via email at DHCFPublicComments@dc.gov, within thirty (30) days of the date of publication of this notice in the *D.C. Register*. Additional copies of these rules are available from the above address.